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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,401	10/19/2000	Leonora Heidecker	L0461/7097-(JRV)	7318

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EXAMINER	
DECLOUX, AMY M	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/692,401	HEIDECKER ET AL.	
	Examiner	Art Unit	
	Amy M. DeCloux	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3-6-02 & 4-5-02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,8,10,16,18-20,34,40-44,46,52,53 and 58-77* is/are pending in the application.

4a) Of the above claim(s) *10,16,18-20,34,40,41,44,46,52 and 53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,8,42,43 and 58-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-6-02 (Paper No. 14) has been entered.

2. Applicant's election of the species of a nonhydrolyzable peptide of D amino acids, is acknowledged. However, because no art was found on the elected species, nor on the remaining recited species, the species requirement has been withdrawn.

3. Claims 1-4, 7-8, 10, 16, 18-20, 34, 40-44, 46, 52-53 and 58-77 are pending. Claims 10, 16, 18-20, 34, 40-41, 44, 46, 52-53 are withdrawn from consideration as being drawn to a non elected invention.

4. In view of Applicant's amendment filed 3-9-02 (Paper No. 14), the outstanding 112 first paragraph rejections have been withdrawn. However, a new ground of rejection has been applied.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3, 7, 42-43, 58-63, 66-68, 70-73 and 75-76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the recited peptides which bind to the HLA class I molecule of HLA Cw*07, does not reasonably provide enablement for the recited peptides which bind to ANY HLA class I molecule.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant claims are drawn to a MAGE-A12 peptide which consists essentially of the peptide of SEQ ID NO:s 4, 5, and 6 which bind to a Class I HLA molecule. However the specification does not disclose isolated MAGE-A12 peptides that bind to HLA class I molecules other than HLA Cw*07. Engelwood discloses that the anchor amino acids within the peptide are important for binding specifically to each MHC Class I molecule (Engelhard page 14, of record). Since the specification does not disclose any HLA Class I

molecule, other than HLA Cw*07, that binds the peptides encompassed by the instant claims, it would require undue experimentation for one of skill to predict which HLA molecule, other than HLA Cw*07, would bind the peptides encompassed by the instant claims, without further guidance from the instant specification.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

7. Claims 1-3, 7, 42-43, 58-63, 66-68, 70-73 and 75-76 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a MAGE-A12 peptide which consists essentially of the peptide of SEQ ID NO:s 4, 5, and 6 which bind to a Class I HLA molecule. However the specification does not disclose isolated MAGE-A12 peptides that bind to HLA class I molecules other than HLA Cw*07. With the exception of HLA Cw*07, there is no description in the instant specification of the required structural features required by the wide range of HLA class I molecules encompassed by the instant claims, for binding the peptides encompassed by the instant claims, or of the conserved regions of HLA class I molecules that would be critical for these features. Further, the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the HLA class I molecules encompassed by the instant claims. Therefore, the structure of a Class I HLA molecule, wherein said HLA class I molecules bind the peptides encompassed by the instant claims, is not conventional in the art, and one of skill in the art would not recognize from the disclosure that applicant was in possession of the genus of an HLA class I molecule that binds the peptides encompassed by the instant claims, with the exception of HLA Cw*07, without further description from the instant specification.

It is noted that though the claimed invention is directed to polypeptides and not cDNA, the principle of the following still holds for said polypeptides: a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly&Co.*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

8. Claims 4, 8, 64-65, 69, 74 and 77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated MAGE-A12 class I binding peptide which binds HLA Cw*07, wherein said peptide consists of a fragment of the amino acid sequence of SEQ ID NO:2, and wherein said fragment consists of SEQ ID NO:4, 5, or 6, does not reasonably provide enablement for an isolated MAGE-A12 class I binding peptide which

binds HLA Cw*07, wherein said peptide consists of ANY fragment of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims encompass an isolated MAGE-A12 class I binding peptide which binds HLA Cw*07 and consists of ANY fragment of SEQ ID NO:2. The specification does not disclose fragments of SEQ ID NO:2 which bind HLA Cw*07, other than the fragments consisting of SEQ ID NO:4, 5, or 6. Engelwood discloses that the anchor amino acids within the peptide are important for binding specifically to each MHC Class I molecule (Engelhard page 14, of record). Since the specification does not disclose any fragments of SEQ ID NO:2 which bind HLA Cw*07, other than the fragments consisting of SEQ ID NO:4, 5, or 6, it would require undue experimentation for one of skill to predict which fragment of SEQ ID NO:2, other than the fragments consisting of SEQ ID NO:4, 5, or 6, would bind HLA Cw*07 , without further guidance from the instant specification.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

9. Claims 4, 8, 64-65, 69, 74 and 77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims encompass an isolated MAGE-A12 class I binding peptide which binds HLA Cw*07 and consists of a fragment of SEQ ID NO:2. However the specification does not disclose fragments of SEQ ID NO:2 which bind HLA Cw*07, other than the fragments consisting of SEQ ID NO:4, 5, or 6. With the exception of the fragments consisting of SEQ ID NO:4, 5, or 6, there is no description in the instant specification of the required structural features required by the wide range of fragments of SEQ ID NO:2 required for binding HLA Cw*07, or of the conserved regions of HLA class I molecules that would be critical for these features. Further, the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the fragments of SEQ ID NO:2 encompassed by the instant claims, other than the fragments consisting of SEQ ID NO:4, 5, or 6. Therefore, the structure of a fragment of SEQ ID NO:2 which binds HLA Cw*07, is not conventional in the art, and one of skill in the art would not recognize from the disclosure that applicant was in possession of the genus of a fragment of SEQ ID NO:2 which binds HLA Cw*07, with the exception of the fragments consisting of SEQ ID NO:4, 5, or 6, without further description from the instant specification.

It is noted that though the claimed invention is directed to polypeptides and not cDNA, the principle of the following still holds for said polypeptides: a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the*

University of California v. Eli Lilly&Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640
January 12, 2003
Amy DeCloux
1-12-03